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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/582,241	PARK ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/09 has been entered.

Claims 1-4 are pending in the present application and they are examined on the merits herein.

Response to Amendment

The rejection under 35 U.S.C. 112, first paragraph, for New Matter was withdrawn in part in light of Applicant's amendment.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***This is a modified rejection.***

Claim 2 recites the limitation "A method for **preparing a threonine-producing strain by defecting the threonine importer from a *Corynebacterium glutamicum* strain having a low threonine requirement as compared to a wild strain of *Corynebacterium glutamicum***", while claim 3 is directed to a threonine-producing strain prepared by the method of claim 2. In the amendments filed on 8/27/08 and 5/5/09, Applicants cited Figures 1-2, pages 4-6 and examples 2-3 as written support for the above limitation of claims 2-3. While the as-filed specification teaches defecting or inactivating endogenous ***thrY* gene** of a threonine-producing strain of *Corynebacterium glutamicum*, specifically the CJ T-2 threonine producing *Corynebacterium glutamicum* recombination strain, to generate the threonine-producing strain CJ T-21 (page 5, lines 19-26 and example 5), the instant specification does not have a written support specifically for the preparation of a threonine-producing strain by simply defecting the threonine importer (**encompassing both a threonine importer protein and a threonine importer gene**) from a *Corynebacterium glutamicum* strain having a low threonine requirement as compared to a wild strain of *Corynebacterium glutamicum* as now claimed. Please also note that the threonine-producing strain CJT-2 **does not require any threonine in the fermentation medium (see Table 2)**. Figures 1-2 and examples 2-3 showed how **a cloned DNA fragment encoding the threonine importer from *Corynebacterium glutamicum* was prepared and isolated; and the approach used to generate a thrY-defective *C. glutamicum* strain**; while example 4 is directed

simply to the preparation of a **thrY-defective strain from the low-threonine-requiring strain CJ L-1 to a high-threonine-requiring strain, but it has nothing to do with the production of threonine and/or increasing the yield of threonine production, by defecting or knocking out the endogenous thrY gene of the strain CJL-1**. In other words, the low threonine requiring *C. glutamicum* strain CJ L-1, the high threonine requiring *C. glutamicum* strain CJ L-11 and the high threonine requiring CJ L-1 strain with its defective thrY gene **are not threonine producing strains**; and that these strains were taught by the instant specification basically for cloning a threonine importer and to verify the function of the cloned threonine importer (pages page 3, line 24 continues to line18 of page 5; and examples 1-4).

Therefore, given the lack of sufficient guidance provided by the originally filed specification, it would appear that Applicants did not contemplate and/or had possession of the instant broadly claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a new ground of rejection.***

In claim 2, as written it does not appear to contain any method step for a method of preparing a threonine-producing strain. The phrase "A method for preparing a

threonine-produing strain by defecting the threonine importer...." Is part of a preamble of the claim without any specific method step being recited in the body of the claim. Accordingly, the metes and bounds of the claim are not clearly determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (US 2002/0197605). ***This is a new ground of rejection.***

Nakagawa et al already disclosed an isolated *Corynebacterium glutamicum* polynucleotide having SEQ ID NO:1 comprising a threonine importer nucleic acid sequence (nucleotides 3,231,051 to 3,232,304) that is 100% identical to the DNA sequence from the 1,772 base to the 3,025 base of SEQ ID NO:1 of the present invention (see at least Summary of the Invention, paragraph 20 and SEQ ID NO:1). Additionally, Nakagawa et al also disclosed an isolated polynucleotide having SEQ ID NO:3350 (1251 nucleotides long) encoding for a proton/glutamate symporter or excitatory amino acid transporter 2 that is 99.8 % identical with 100% local similarity to the DNA sequence from the 1,772 base to the 3,025 base of SEQ ID NO:1 of the present invention (see Table 1). It is noted that the isolated polynucleotide of SEQ ID

NO:1 or SEQ ID NO:3350 of Nakagawa et al was a cloned DNA; and that SEQ ID NO:3350 consists of an encoded sequence for a threonine importer sequence encoded by a contiguous DNA sequence from the 1,772 base to the 3,025 base of SEQ ID NO:1 of the present invention.

Please, also note that where, as here, the claimed and prior art products are identical **or** substantially identical, **or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the teachings of Nakagawa et al meet every limitation of the claims as written. Therefore, the reference anticipates the instant claims.

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed on 5/5/09 (pages 5-7) have been fully considered but they are respectfully not found persuasive for the following reasons.

Once again, Applicants argue basically that the Nakagawa et al reference does not teach the defined nucleic acid sequence corresponding solely to the threonine importer gene nor does it mention about a threonine importer gene, while the present invention is drawn to a defined nucleic acid sequence corresponding solely to the threonine importer gene from *Corynebacterium gluctamicum* and not the entire genome. Additionally, Applicants argue that the Nakagawa et al reference is neither enabled nor satisfied the utility requirement, nor does the reference renders the presently claimed invention obvious.

First, please note that as written claim 1 encompasses an isolated DNA clone encoding a threonine importer from *C. glutamicum*, as long as it **comprises** nucleotides 1772 through 3,025 among other nucleotides of SEQ ID NO. 1 (4846 nucleotides); and as such the claim also encompasses an isolated *Corynebacterium glutamicum* DNA clone of SEQ ID NO:1 taught by Nakagawa et al.

Second, the isolated *Corynebacterium glutamicum* DNA clone of SEQ ID NO:1 taught by Nakagawa et al encompasses a contiguous DNA sequence from 1,772 base through 3,025 base among DNA sequences in SEQ ID NO:1 of the present invention; and that this DNA clone was already successfully isolated and described by Nakagawa et al and therefore the reference is clearly enabled.

Third, the above rejection was made under 35 U.S.C. 102(b) and therefore Applicant's arguments related to utility and obviousness are irrelevant and moot.

Fourth, the examiner suggests the following claim amendment for overcoming the teachings of Nakagawa et al. ***- - An isolated DNA molecule encoding a***

threonine importer from Corynebacterium glutamicum, wherein said DNA molecule consists of nucleotides 1,772 to 3,025 of SEQ ID NO:1. - -.

Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Pompejus et al. (US 6,696,561). ***This is a new ground of rejection.***

The claim is drawn to an isolated DNA clone encoding a threonine importer consisting of **a sequence** encoded by a contiguous DNA sequence from the 1772 base to the 3,025 base among DNA sequences with the SEQ ID NO:1. It is noted that as written, the claim is not necessarily limited that the isolated DNA clone encoding **the threonine importer consisting of the sequence encoded by nucleotides 1772 through 3,025 of SEQ ID NO:1**; and as such the following rejection is applied.

Pompejus et al already disclosed an isolated nucleic acid sequence of SEQ ID NO:543 (1058 nucleotides in length) encoding a proton/sodium-glutamate symport protein from *Corynebacterium glutamicum* that is 81.8% similarity or 99.8% local similarity to nucleotides 1772-2810 of SEQ ID NO:1 of the present invention (see at least the abstract; Table 1 on page 62; RXN00960 on page 324 and 482). It is noted that NO:543 is a cloned DNA; and the SEQ ID NO:543 consists of an encoded sequence for a threonine importer sequence encoded by a contiguous DNA sequence from the 1772 base to the 3,025 base among DNA sequences with the SEQ ID NO:1.

Accordingly, the teachings of Pompejus et al meet the limitation of the instant claim as broadly written. Therefore, the reference anticipates the claim as written.

Response to Arguments

Applicants' arguments with respect to the above rejection in the Amendment filed on 5/5/09 (page 7) have been fully considered but they are respectfully not found persuasive.

Applicants argue basically that the teachings of Pompejus et al do not meet all the limitations of claims 4, specifically uses of the terms "consisting of" and drawn to the entire region of the 1,772 base to the 3,025 base among DNA sequences with the SEQ ID NO:1.

First, as written, claim 4 claim **is not necessarily limited that the isolated DNA clone encoding the threonine importer consisting of the sequence encoded by nucleotides 1772 through 3,025 of SEQ ID NO:1.** Accordingly, the teachings of Pompejus et al anticipate the claim as written for the reasons discussed above.

Second, the examiner suggests the following claim amendment for overcoming the teachings of Pompejus et al. ***- - An isolated DNA molecule encoding a threonine importer, wherein said DNA molecule consists of nucleotides 1,772 to 3,025 of SEQ ID NO:1 - -.***

Claims 2-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmieri et al (Arch Microbiol. 165:48-54, 1996) as evidenced by Park et al. (US 2008/0026432). ***This is a new ground of rejection.***

Palmieri et al already disclosed a method in which *C. glutamicum* MH20-22B and MH20-22B DR17 strains being exposed to various conditions such as excess of serine, N-ethyl-maleimide (NEM) plus HgCl2, carbonyl cyanide m-chlorophenylhydrazone, all of which **inhibit threonine uptake** (see at least Table 1; page 51, col. 1, first paragraph; page 52, col. 1, second paragraph and Fig. 5); and therefore fall within a broad scope of "defecting the threonine importer from *C. glutamicum* strain", and that the *C. glutamicum* threonine importer would be encoded by nucleotides 1772 to 3,025 of SEQ ID NO:1 as evidenced by the teachings of Park et al. (see at least example 3). Additionally, both of these *C. glutamicum* strains do not require threonine for growth (page 49, col. 1, last paragraph continues to first paragraph of col. 2); and therefore they also fall within a broad scope of "having a low threonine requirement".

Accordingly, the teachings of Palmieri et al meet the limitation of the claims as broadly written. Therefore, the reference anticipates the instant claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Okamoto et al. (Biosci. Biotech. Biochem. 61:1877-1882, 1997 disclosed hyperporduction of L-threonine by an *Escherichia coli* mutant with impaired L-threonine uptake (see at least the abstract).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/QUANG NGUYEN/

Primary Examiner, Art Unit 1633